CLAIMS

What is claimed is:

1. A method of monitoring the therapeutic inactivating capacity of a subject, said method comprising:

a) obtaining a sample from a subject to be monitored;

b) assessing said sample for a therapeutic inactivating component specific for a therapeutic agent that has been administered, is being administered or will be administered to said subject, wherein said therapeutic inactivating component binds with said therapeutic agent and interferes with the utility of said therapeutic agent, with a *proviso* that when said therapeutic inactivating component is an antibody, said antibody is not assessed via plasmon resonance; and

c) deciding to initiate, terminate, or adjust the level of administration of said therapeutic agent to said subject based on said assessed therapeutic inactivating component.

2. The method of claim 1, wherein the subject is afflicted by or believed to be afflicted by a medical condition.

3. The method of claim 2, wherein the therapeutic agent is useful for treating the medical condition or the underlying symptomology of the medical condition.

4. The method of claim 1, wherein the therapeutic agent is selected from the group provided in Table 2.

5. The method of claim 3, wherein the therapeutic agent is selected from the group consisting of a pain management agent, an antipyretic agent, a migraine agent, a prophylaxis agent, an anti-infective agent, an (anti-)inflammatory agent, an (anti-)parasitic agent, a uterine agent, a (anti-) microbial agent, an (anti-)arthritic agent, a gout related agent, a cardiovascular agent, a cancer agent, an immunomodulation agent, a metabolic agent, a musculoskeletal agent, a (anti-)toxicity agent, a dermatologic agent, an ophthalmic agent, an otic agent, a pharyngeal agent, a nasal agent, an HIV or AIDS related agent, an allergy or asthma related agent, an Alzheimer's disease related agent, a diabetes related agent, a glandular disorder related agent, a kidney disease related agent, a liver disease related agent, a mental health related agent, an osteoporosis related agent, a Parkinson's disease related agent, an osteoporosis related agent, a renal bone disease agent, an agent to treat disorders of the parathyroid gland, a sexually transmitted disease related agent, a stroke related agent, a blood or circulatory related agent, an endocrine related agent, a gastrointestinal agent, a neurological agent, and a respiratory agent.

6. The method of claim 3, wherein the medical condition is selected from the group consisting of a pain management related condition, a migraine related condition, an infection, an

inflammatory related condition, a urinary related condition, an OB/GYN disorder, an arthritic related condition, a foot related condition, a cardiovascular related condition, a metabolic related condition, a musculoskeletal related condition, cancer, an immunological related condition, a toxicity related condition, a dermatologic related condition, an ophthalmic related condition, an otic related condition, a pharyngeal related condition, a nasal related condition, a blood or circulatory related condition, AIDS, allergy & asthma, Alzheimer's disease, a child specific condition, diabetes, a glandular disorder, kidney disease, liver disease, mental health related condition, osteoporosis, renal bone disease, Parkinson's disease, a sexually transmitted disease, stroke, an endocrine related condition, a gastrointestinal related condition, a neurological related condition, and a respiratory related condition.

7. The method of claim 1, wherein multiple therapeutic agents are identified and the biological sample is assessed for a therapeutic inactivating component specific for a selection of the therapeutic agent(s).

8. The method of claim 1, wherein the interference with the utility of said therapeutic agent comprises reduced or eliminated efficacy, or an adverse biological reaction to the therapeutic agent.

9. The method of claim 8, wherein the adverse biological reaction comprises the generation of an immune response to the therapeutic agent.

10. The method of claim 1, wherein the presence or absence of the therapeutic inactivating component is assessed.

11. The method of claim 1, wherein the level of the therapeutic inactivating component is assessed.

12. The method of claim 1, wherein the therapeutic inactivating component is assessed by a sandwich or competitive assay format.

13. The method of claim 1, wherein the therapeutic inactivating component is assessed by a format selected from the group consisting of an enzyme-linked immunosorbent assay (ELISA), immunoblotting, immunoprecipitation, radioimmunoassay (RIA), immunostaining, latex agglutination, indirect hemagglutination assay (IHA), electron transfer assay, complement fixation, indirect immunofluorescent assay (IFA), nephelometry, flow cytometry assay, chemiluminescence assay, lateral flow immunoassay, u-capture assay, inhibition assay and avidity assay.

14. The method of claim 1, wherein the therapeutic agent is a small molecule or biomolecule.

15. The method of claim 1, wherein the therapeutic agent is recombinant erythropoietin or an erythropoietin analog.

16. The method of claim 1, wherein the therapeutic inactivating component is an antibody or antibody fragment.

17. The method of claim 2, wherein the therapeutic agent is available for treating the medical condition, and the decision to initiate, terminate, or adjust the level of any one of the one or more therapeutic agents is based on said assessed therapeutic inactivating component.

18. The method of claim 1, wherein the decision for initiating, terminating or adjusting the level of administration of the therapeutic agent to the subject is made by a health care provider or a personnel of a health care management entity.

19. The method of claim 18, wherein the health care provider is a clinician or a nurse.

20. The method of claim 1, which is conducted in a clinical lab.

21. The method of claim 1, wherein the therapeutic agent is selected from the group consisting of atorvastatin, epoetin alfa, paricalcitol, risperidone, a calcimemetic, furosemide, a bisphosphanate, and teriparatide.

22. The method of claim 1, wherein the subject has previously received and is currently receiving administration of the therapeutic agent, wherein the therapeutic inactivating component is an antibody, and wherein the sample is assessed for the presence or absence of the antibody.

23. The method of claim 22, wherein the subject is monitored over a prolonged period of treatment with the therapeutic agent for the development of the antibody.

24. The method of claim 23, wherein the therapeutic agent is recombinant erythropoietin or an erythropoietin analog.

25. The method of claim 1, wherein the sample is assessed via steps comprising:

a) contacting the sample containing the therapeutic inactivating component, if any, with the therapeutic agent to form a reaction mixture, wherein the therapeutic agent comprises an unhindered form of the therapeutic agent bound by a low molecular weight label, and wherein the therapeutic inactivating component, if any, binds the unhindered, labeled therapeutic agent to form a labeled therapeutic inactivating component complex;

b) separating the labeled therapeutic inactivating component complex from the reaction mixture; and

c) assessing the separated labeled therapeutic inactivating component complex.

26. The method of claim 25, wherein the proportion of the molecular weight of the low molecular weight label bound to the unhindered therapeutic agent, versus the molecular weight of the unhindered therapeutic agent itself, comprises less than about 50%.

27. A method for determining or monitoring a therapeutic protocol for a subject afflicted with an auto antibody specific for a natural substance, wherein said auto antibody developed as a result of therapeutic administration of the natural substance or an analog thereof, said method comprising:

a) obtaining a sample from said subject;

b) assessing said sample for the presence and/or level of said natural substance;

c) assessing said sample for the presence of said auto antibody that specifically binds said natural substance, wherein said auto antibody is not assessed via plasmon resonance or a competitive assay, and said natural substance is not insulin or thyroglobulin; and

d) deciding to initiate, terminate, or adjust the level of administration of the natural substance to said subject based on said assessed auto antibody.

28. The method of claim 27, wherein the natural substance is useful for treating the medical condition or the underlying symptomology of the medical condition.

29. The method of claim 27, wherein the natural substance is selected from the group provided in Table 2.

30. The method of claim 27, wherein the presence or absence of the auto antibody is assessed.

31. The method of claim 27, wherein the auto antibody is assessed by a sandwich assay format.

32. The method of claim 27, wherein the decision for initiating, terminating or adjusting the level of administration of the therapeutic agent to the subject is made by a health care provider or a personnel of a health care management entity.

33. The method of claim 27, which is conducted in a clinical lab.

34. The method of claim 27, wherein the natural substance is parathyroid hormone (PTH).

35. The method of claim 27, wherein the therapeutic agent comprises a compound having an antagonistic biological effect to that normally exhibited by the natural substance.

36. The method of claim 27, wherein the auto antibody is specific for a receptor involved in a biological pathway affected by the natural substance.

37. The method of claim 36, wherein the receptor is a calcium sensing receptor and the natural substance is PTH.

38. The method of claim 27, wherein the natural substance is erythropoietin.

39. The method of claim 27, wherein the sample is assessed for the presence of the auto antibody via steps comprising:

a) contacting the sample containing the auto antibody, if any, with the natural substance to form a reaction mixture, wherein the natural substance comprises an unhindered form of the natural substance bound by a low molecular weight label, and wherein the auto antibody, if any, binds the unhindered, labeled natural substance to form a labeled auto antibody complex;

b) separating the labeled auto antibody complex from the reaction mixture; and

c) assessing the separated labeled auto antibody complex.

40. The method of claim 39, wherein the proportion of the molecular weight of the low molecular weight label that is capable of binding the unhindered natural substance, versus the molecular weight of the unhindered natural substance itself, comprises less than about 50%.

41. A method for determining or monitoring a therapeutic protocol for a subject receiving or about to receive administration of a chemical moiety-based therapeutic agent, said method comprising:

a) obtaining a sample from said subject;

b) assessing said sample for a therapeutic inactivating component specific for said chemical moiety-based therapeutic agent that has been administered, is being administered or will be administered to said subject, wherein said therapeutic inactivating component binds with said chemical moiety-based therapeutic agent and interferes with the utility of said therapeutic agent; and

c) deciding to initiate, terminate, or adjust the level of administration of said chemical moiety-based therapeutic agent to said subject based on said assessed therapeutic inactivating component.

42. The method of claim 41, wherein the chemical moiety-based therapeutic agent is a small molecule.

43. The method of claim 41, wherein the chemical moiety-based therapeutic agent is a prescription drug or an over the counter drug.

44. The method of claim 41, wherein the presence or absence of the therapeutic inactivating component is assessed.

45. The method of claim 41, wherein the decision for initiating, terminating or adjusting the level of administration of the chemical moiety-based therapeutic agent to the subject is made by a health care provider or a personnel of a health care management entity.

46. The method of claim 41, which is conducted in a clinical lab.

47. The method of claim 41, wherein the subject has previously received and is currently receiving administration of the chemical moiety-based therapeutic agent, wherein the therapeutic inactivating component is an antibody, and wherein the sample is assessed for the presence or absence of the antibody.

48. The method of claim 47, wherein the subject is monitored over a prolonged period of treatment with the chemical moiety-based therapeutic agent for the development of the antibody.

49. The method of claim 41, wherein the sample is assessed via steps comprising:

a) contacting the sample containing the therapeutic inactivating component, if any, with the chemical moiety-based therapeutic agent to form a reaction mixture, wherein the chemical moiety-based therapeutic agent comprises an unhindered form of the chemical moiety-based therapeutic agent bound by a low molecular weight label, and wherein the therapeutic inactivating component, if any, binds the unhindered, labeled chemical moiety-based therapeutic agent to form a labeled therapeutic inactivating component complex;

b) separating the labeled therapeutic inactivating component complex from the reaction mixture; and

c) assessing the separated labeled therapeutic inactivating component complex.

50. The method of claim 49, wherein the proportion of the molecular weight of the low molecular weight label that is capable of binding the unhindered chemical moiety-based therapeutic agent, versus the molecular weight of the unhindered chemical moiety-based therapeutic agent itself, comprises less than about 50%.

51. A kit for monitoring therapeutic inactivating capacity of a subject, which kit comprises:

a) a means for assessing therapeutic inactivating component of a sample obtained from a subject to a therapeutic agent that has been administered, is being administered or will be administered to said subject; and

b) instructions for making a decision for initiating, terminating or adjusting the level of administration of said therapeutic agent to said subject based on said assessed therapeutic inactivating component.

52. The kit of claim 51, which further comprises a means for obtaining a sample from a subject to be monitored.

53. The kit of claim 51, wherein the therapeutic agent is selected from those listed in Table 2.

54. The kit of claim 51, wherein the means for assessing a therapeutic inactivating component comprises an unhindered therapeutic agent, and a low molecular weight label bound to the unhindered therapeutic agent.

55. The kit of claim 51, wherein the proportion of the molecular weight of the low molecular weight label that is capable of binding the unhindered therapeutic agent, versus the molecular weight of the unhindered therapeutic agent itself, comprises less than about 50%.

56. A kit comprising:

a) a therapeutic agent; and

b) instructions for monitoring the therapeutic inactivating capacity of a subject to said therapeutic agent.

57. The kit of claim 56, wherein the therapeutic agent is an unhindered therapeutic agent, and the kit further comprises a low molecular weight label bound to the unhindered therapeutic agent.

58. A method of monitoring the hormone inactivating capacity of a subject, said method comprising:

a) obtaining a sample from a subject to be monitored;

b) assessing said sample for a hormone inactivating component specific for a hormone, wherein said hormone inactivating component binds with said hormone and interferes with the normal biological activity of said hormone; with a *proviso* that when said hormone inactivating component is an antibody, said antibody is not assessed via plasmon resonance, and

a further *proviso* that when said hormone is insulin or thyroglobulin, said hormone inactivating component is not an auto antibody; and

c) deciding to initiate, terminate, or adjust the level of therapeutic administration of said hormone to said subject based on said assessed hormone inactivating component.

59. The method of claim 58, wherein the hormone is recombinant erythropoietin or erythropoietin analog and said hormone inactivating component is an antibody specific for the recombinant erythropoietin or erythropoietin analog.

60. The method of claim 58, wherein the subject has previously received and is currently receiving administration of the hormone, wherein the therapeutic inactivating component is an antibody, and wherein the sample is assessed for the presence or absence of the antibody.

61. The method of claim 60, wherein the subject is monitored over a prolonged period of treatment with the hormone for the development of the antibody.

62. The method of claim 61, wherein the hormone is recombinant erythropoietin or an erythropoietin analog.

63. The method of claim 58, wherein the sample is assessed via steps comprising:

a) contacting the sample containing the hormone inactivating component, if any, with the hormone to form a reaction mixture, wherein the hormone comprises an unhindered form of the hormone bound by a low molecular weight label, and wherein the hormone inactivating component, if any, binds the unhindered, labeled hormone to form a labeled hormone inactivating component complex;

b) separating the labeled hormone inactivating component complex from the reaction mixture; and

c) assessing the separated labeled hormone inactivating component complex.

64. The method of claim 63, wherein the proportion of the molecular weight of the low molecular weight label that is capable of binding the unhindered hormone, versus the molecular weight of the unhindered hormone itself, comprises less than about 50%.